

Making Part D Access Affordable

House of Representatives Redesign Options

February 2020



Introduction

- Policymakers are discussing ways to limit the out-of-pocket expenses faced by non-low income subsidy (LIS) patients in the Medicare prescription drug benefit (Part D) to make prescriptions more affordable
- This work was done on behalf of the Council for Affordable Health Coverage* who has worked on making Part D more affordable for Medicare beneficiaries
 - The CAHC is a broad-based alliance with a singular focus: bringing down the cost of health coverage for all Americans
 - CAHC membership represents a broad range of interests – organizations representing small and large employers, manufacturers, retailers, insurers, patient groups, and physician organizations

* Editorial control was maintained by Xcenda.

Revisiting the Part D Benefit Structure

- Since the Medicare prescription drug benefit (Part D) was implemented in 2006, utilization of drugs has evolved
- While there is high generic utilization, specialty tiers and use of coinsurance has increased, creating affordability challenges for beneficiaries
 - According to the Kaiser Family Foundation, over 1 million non-low income beneficiaries had spending in the catastrophic phase of the benefit in 2017
 - On average, their out-of-pocket spending is more than six times higher than spending incurred by beneficiaries not reaching the catastrophic phase and not receiving a low income subsidy
 - Patients who do not reach the catastrophic phase often also struggle to afford cost sharing of hundreds of dollars a month or more
- Congress has advanced several pieces of legislation to reform the benefit design

Part D Benefit Design Reform Bills

H.R. 3

H.R. 19

116TH CONGRESS
1ST SESSION

H. R. 3

AN ACT

To establish a fair price negotiation program, protect the Medicare program from excessive price increases, and establish an out-of-pocket maximum for Medicare part D enrollees, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

2

1 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

2 (a) **SHORT TITLE.**—This Act may be cited as the
3 “Elijah E. Cummings Lower Drug Costs Now Act”.

4 (b) **TABLE OF CONTENTS.**—The table of contents is
5 as follows:

Sec. 1. Short title; table of contents.

**TITLE I—LOWERING PRICES THROUGH FAIR DRUG PRICE
NEGOTIATION**

Sec. 101. Providing for lower prices for certain high-priced single source drugs.

Sec. 102. Selected drug manufacturer excise tax imposed during noncompliance periods.

Sec. 103. Fair Price Negotiation Implementation Fund.



116TH CONGRESS
1ST SESSION

H. R. 19

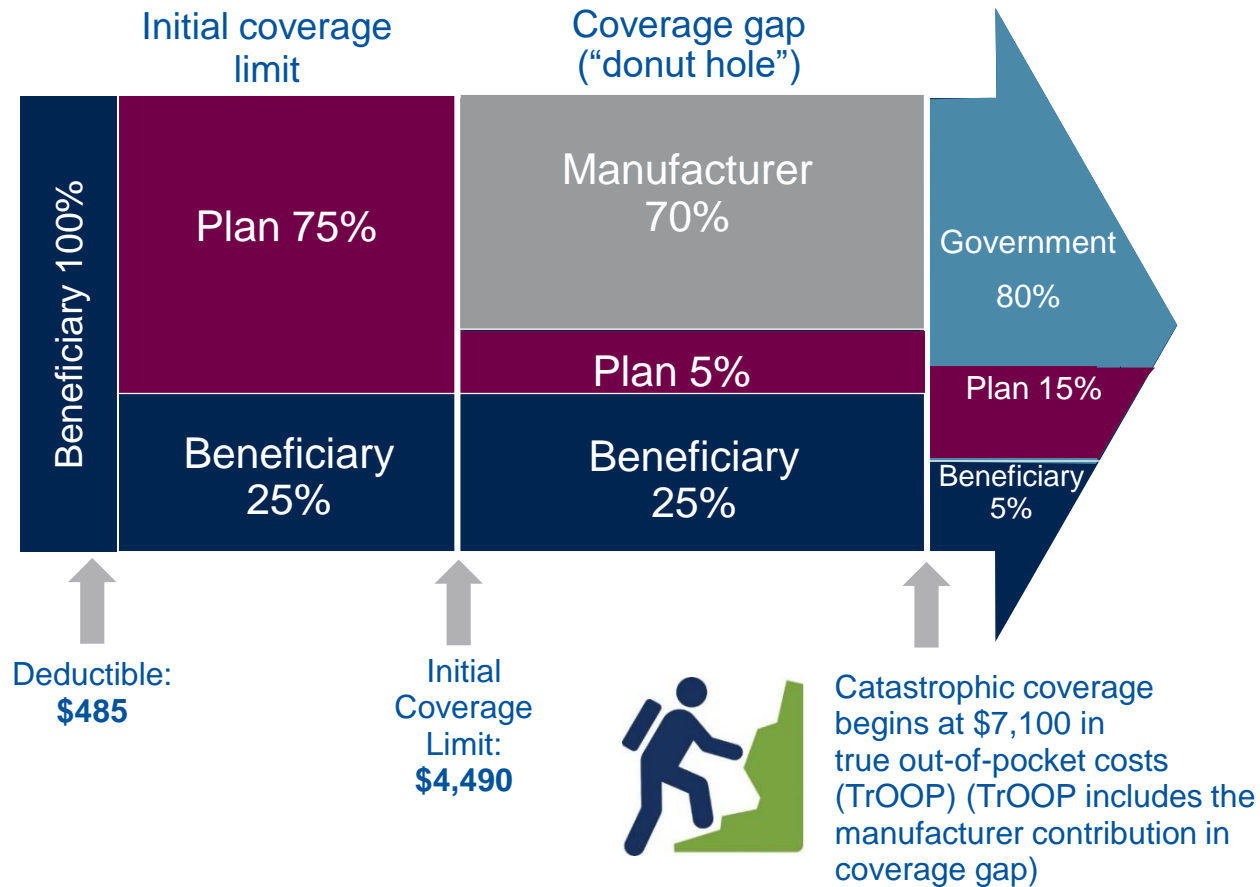
To provide for certain reforms with respect to the Medicare program under title XVIII of the Social Security Act, the Medicaid program under title XIX of such Act, the Food and Drug Administration, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

DECEMBER 9, 2019

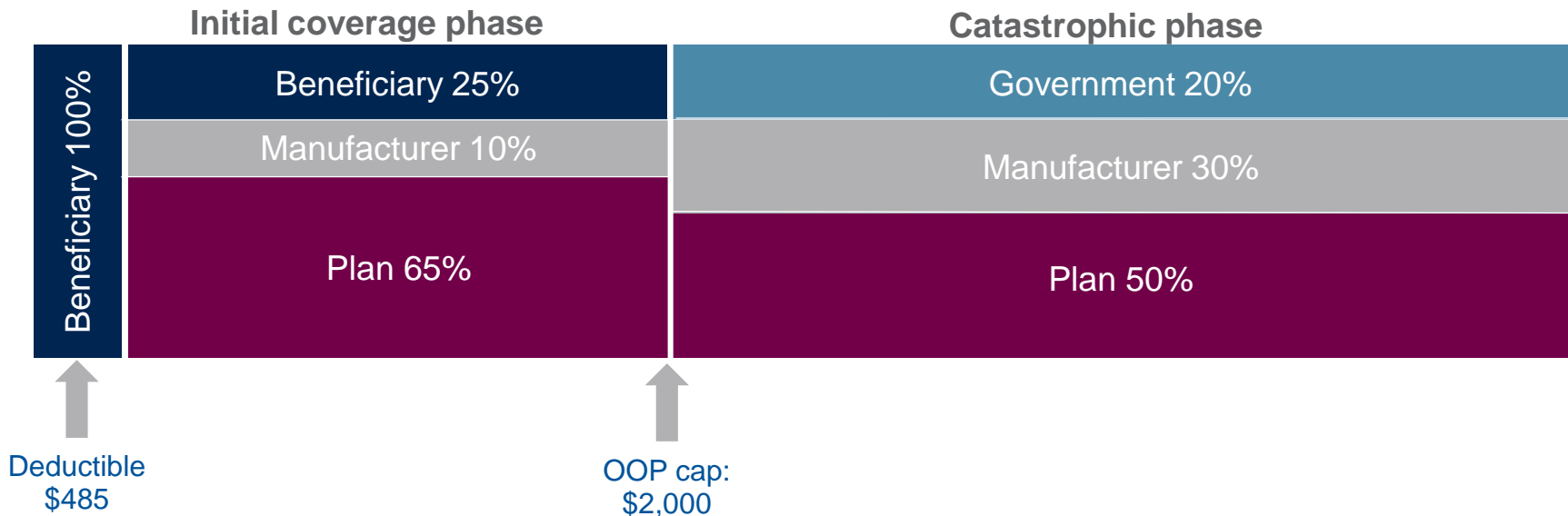
Mr. WALDEN (for himself, Mr. BRADY, Ms. FOXX of North Carolina, Mr. COLLINS of Georgia, Mr. BURGESS, Mr. NUNES, Mr. WALBERG, Mr. SENSENBRENNER, Mr. SCALISE, Ms. CHENEY, Mr. UPTON, Mr. SHIMKUS, Mr. LATTA, Mr. GUTHRIE, Mrs. RODGERS of Washington, Mr. OLSON, Mr. MCKINLEY, Mr. KINZINGER, Mr. GRIFFITH, Mr. BILIRAKIS, Mr. JOHNSON of Ohio, Mr. LONG, Mr. BUCSHON, Mr. FLORES, Mrs. BROOKS of Indiana, Mr. MULLIN, Mr. HUDSON, Mr. CARTER of Georgia, Mr. GIANFORTE, Mr. PALMER, Mr. COLE, Mr. WILLIAMS, Mr. ABRAHAM, Mr. KELLER, Mr. RUTHERFORD, Mr. FERGUSON, Mr. KUSTOFF of Tennessee, Mr. RIGGLEMAN, Mr. WESTERMAN, Mr. GRAVES of Louisiana, Mr. LAMALLEA, Mr. BAIRD, Mr. HUIZENGA, Mr. MURPHY of North Carolina, Mr. CONAWAY, Mr. ALLEN, Mr. WEBER of Texas, Mr. NEWHOUSE, Mr. BABIN, Mr. HAGEDORN, Mr. ROUZER, Mr. RICE of South Carolina, Mr. WILSON of South Carolina, Mr. PENCE, Mr. HILL of Arkansas, Mr. MARSHALL, Mr. BALDERSON, Mr. ADERHOLT, Mr. RODNEY DAVIS of Illinois, Mr. MITCHELL, Mr. CRENSHAW, Mr. JOYCE of Pennsylvania, Mr. JOHNSON of South Dakota, Mr. GREEN of Tennessee, Mrs. MILLER, Ms. STEFANIK, Mr. BANKS, Mr. COMER, Mr. MCCAUL, Mr. DIAZ-BALART, Mr. AMODEI, Mr. NORMAN, Mr. DAVID P. ROE of Tennessee, Mr. BUDD, Mr. COOK, Mr. KEVIN HERN of Oklahoma, Mr. CHABOT, Mr. STRUBE, Mr. CURTIS, Mr. GROTHMAN, Mr. STEIL, Mr. JOYCE of Ohio, Mr. SMITH of New Jersey, Mr. GONZALEZ of Ohio, Mr. STAUBER, Mr. BUCHANAN, Mr. SMITH of Nebraska, Mr. ARRINGTON, Mr. MARCHANT, Mrs. WALORSKI, Mr. KELLY of Pennsylvania, Mr. SMITH of Missouri, Mr. LAHOOD, Mr. HOLDING, Mr. ESTES, Mr. REED, Mr. SCHWEIKERT, Mr.

2022 Part D Benefit Design for Branded Drugs, Non-Low Income Beneficiaries



1. CMS. Announcement of Calendar Year (CY) 2020 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter. <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvgtgSpecRateStats/Downloads/Announcement2020.pdf>. Accessed December 3, 2019.
2. CMS. The 2019 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds. <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/Downloads/TR2019.pdf>. Accessed December 3, 2019. 2/12/2020
- 5

H.R. 3: Branded Drugs, 2022, Non-Low Income Beneficiaries

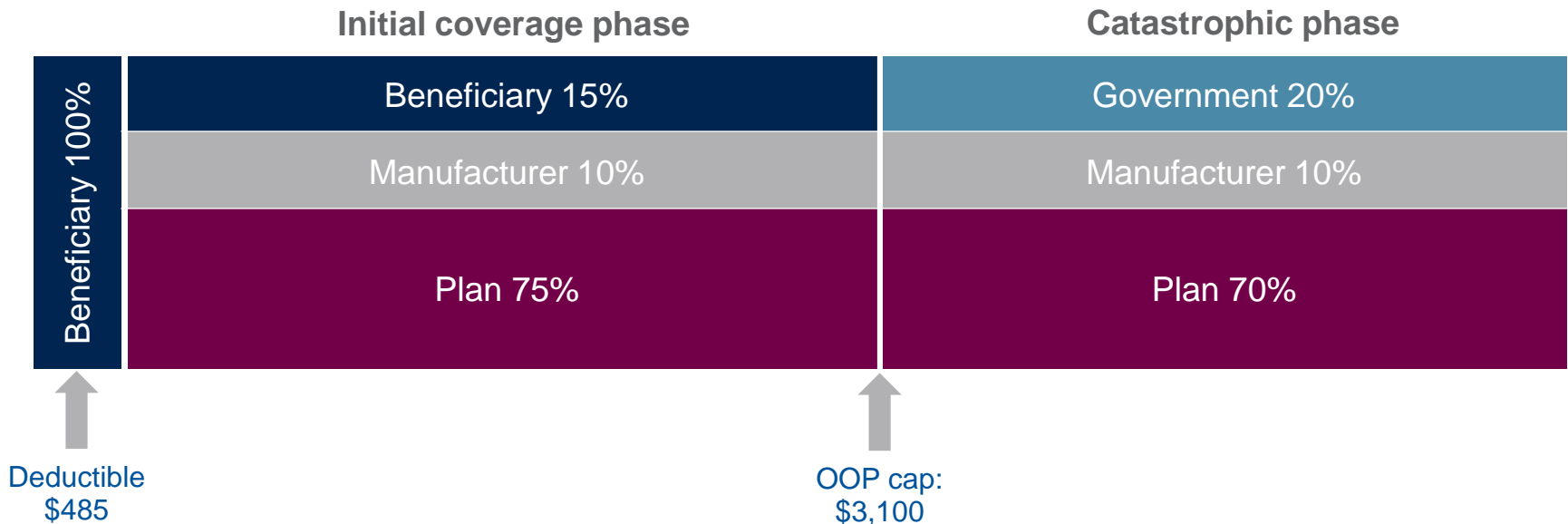


H.R. 3 eliminates the coverage gap and creates an out-of-pocket cap at \$2,000 for non-LIS beneficiaries. Beneficiaries would still pay 25% coinsurance after the deductible and prior to the catastrophic phase. Brand manufacturers would be required to pay a 10% discount in the initial coverage phase and a 30% discount in the catastrophic for both the LIS and non-LIS. Plan liability would be set at 65%, lower than their current liability in the initial coverage phase, but higher than their liability in the current coverage gap for brand medicines.

NOTE: In 2023 and beyond, drugs subject to price negotiation under Title 1 are exempt for manufacturer discounts under the redesign.

<https://www.congress.gov/bill/116th-congress/house-bill/3/text> Accessed January 28, 2020

H.R. 19: Branded Drugs, 2022, Non-Low Income Beneficiaries



The H.R. 19 redesign is similar to H.R. 3, but the manufacturer contribution is set at 10% (for both non-LIS and LIS) in both the initial coverage period and catastrophic period; the beneficiary contribution is the lowest in this design at 15%. The out-of-pocket cap is set at \$3,100, which is approximately what a beneficiary would spend out-of-pocket to reach the catastrophic phase under current law in 2022.

Potential Impact of Changes on Patient OOP

- In order to gauge the impact of the various proposals on patient OOP, Xcenda built patient profiles of example patients with various conditions
- Assumptions
 - OOP cap set at \$2,000 (H.R. 3) and \$3,100 (H.R. 19). This is the amount non-LIS beneficiaries will spend to reach the catastrophic phase in 2022
 - Pharmaceutical profiles were built by a pharmacist
 - Premiums were not factored into OOP
 - Drug prices were obtained through Medicare.gov using the 2020 standard benefit design for standalone prescription drug plans (PDPs) in the example patient profile's area
 - 2020 drug prices were increased by 11.8% to estimate drug costs in 2022. This reflects the increase seen in the benefit design in the Medicare Trustees Report.
 - Impacts of other provisions of the bills (such as Title 1 of H.R. 3 or potential spreading out beneficiary OOP liability over multiple months) and other provisions/implications (impact on innovation) are not reflected in the profiles

Additional Assumptions: Impact on Innovation

- H.R. 3 also includes a number of other provisions that would have a significant impact on the pharmaceutical industry, including government price setting based on international reference prices for certain top medicines and penalties for medicines whose prices grow faster than inflation
- The White House Council of Economic Advisors (CEA) estimated that, as a whole, H.R. 3 could result in as many as 100 fewer drugs entering the US market over the next 10 years*
- Because this analysis is limited to 2022 (prior to the implementation of price setting), the patient outcomes shown here do not include the impact of fewer new treatments

* <https://www.whitehouse.gov/articles/house-drug-pricing-bill-keep-100-lifesaving-drugs-american-patients/>

Comparing Patient OOP for the “Average” Patient

- The “average” patient would also benefit from the Part D redesign, particularly in H.R. 19
 - An average non-LIS beneficiary who reaches catastrophic coverage in 2022 would benefit from the out-of-pocket cap, saving:
 - \$2,080/year under H.R. 3 compared to current law
 - \$980/year under H.R. 19 compared to current law
 - But, in H.R. 19, even the average non-LIS beneficiary who does not reach catastrophic in 2022 would save due to reduced upfront cost-sharing:
 - \$155/year under H.R. 19 compared to current law and H.R. 3
- Patient profiles show how Medicare beneficiaries with specific conditions would fare under the proposals

NOTE: Savings do not include changes in premiums that may occur due to these benefit design changes.
Using 2017 Medicare Current Beneficiary Survey (MCBS)

Comparing Annual Patient OOP Across Models*

	Baseline 2022	H.R. 3	H.R. 19
High cholesterol/ High blood pressure	\$1,445	\$1,445	\$1,060
Type 2 Diabetes	\$1,930	\$1,930	\$1,355
COPD	\$2,170	\$2,000	\$1,495
Hypertension/Afib	\$2,730	\$2,000	\$1,835
HIV	\$4,905	\$2,000	\$3,100
Metastatic Breast Cancer	\$10,890	\$2,000	\$3,100
Average Non-LIS reaching catastrophic	\$4,080	\$2,000	\$3,100
Average Non-LIS not reaching catastrophic	\$870	\$870	\$715

H.R. 3: Patients will hit OOP cap with \$6,545 in total drug spending and \$2,000 in out-of-pocket spending

H.R. 19: Patients will hit OOP cap with \$17,918 in total drug spending and \$3,100 in out-of-pocket spending

Patient's cost savings compared to baseline ranges from:

- \$0 to \$8,890 in H.R. 3
- \$155 to \$7,790 in H.R. 19

Green indicates OOP cap hit

* Savings do not include changes in premiums that may occur due to these benefit design changes.

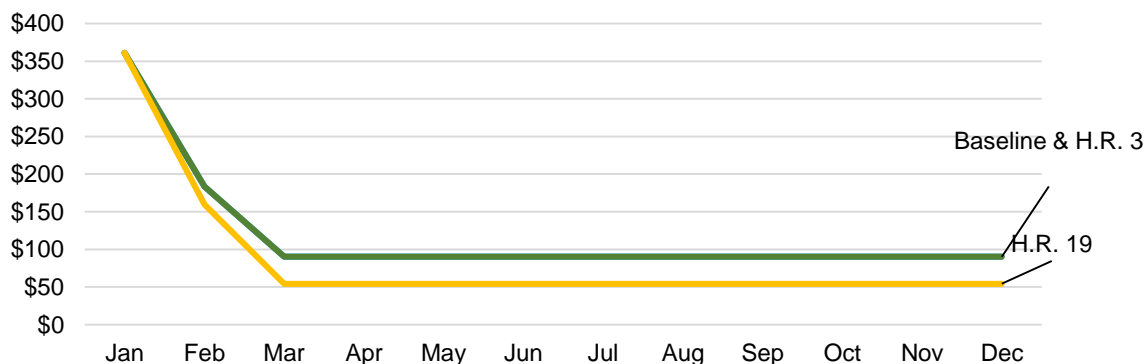
High Cholesterol/High Blood Pressure

Patient	Lisa, age 74 from Tulsa, Oklahoma
Disease Profile	Lisa has high blood pressure and high cholesterol
Medications	<ul style="list-style-type: none"> • Branded product for high cholesterol • Generic product for high blood pressure

Estimated Total Patient Out-of-Pocket Costs for 2022

Baseline 2022	H.R. 3	H.R. 19
\$1,445	\$1,445	\$1,060
<i>Cost Savings Compared to Baseline</i>		
<i>Baseline</i>	\$0	-\$385

Lisa's Month-to-Month OOP Costs (High Cholesterol/High Blood Pressure)



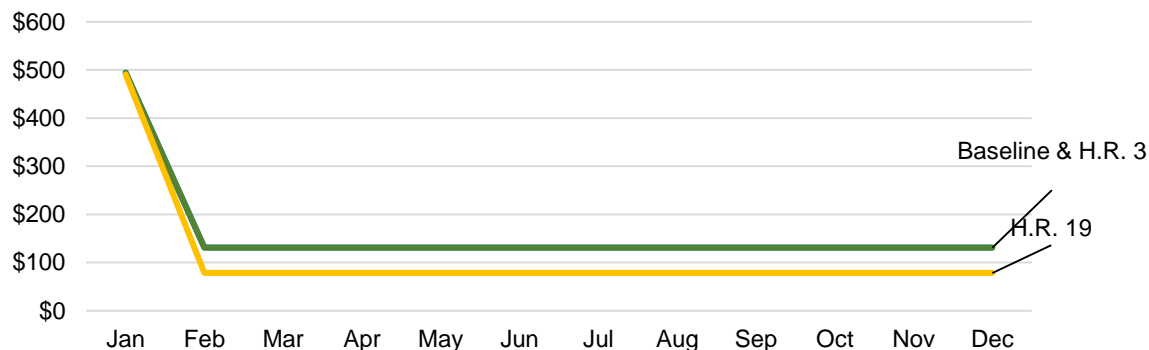
Type 2 Diabetes Mellitus

Patient	Tim, age 72 from Chicago, Illinois
Disease Profile	In addition to diabetes, Tim has high cholesterol and high blood pressure
Medications	<ul style="list-style-type: none"> • Branded product for diabetes • Generic products for diabetes, renal protection, high blood pressure, and high cholesterol

Estimated Total Patient Out-of-Pocket Costs for 2022

Baseline 2022	H.R. 3	H.R. 19
\$1,930	\$1,930	\$1,355
<i>Cost Savings Compared to Baseline</i>		
<i>Baseline</i>	\$0	-\$575

Tim's Month-to-Month OOP Costs (Type 2 Diabetes)



Note: Does not reflect \$50 post-deductible cap for insulin and insulin supplies included in H.R. 19.

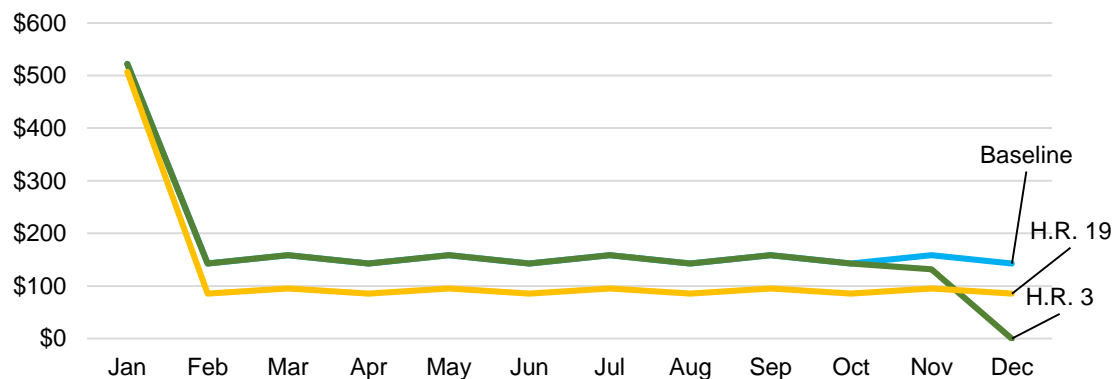
Chronic Obstructive Pulmonary Disorder (COPD)

Patient	Sandy, age 75 from Mountain View, California
Disease Profile	In addition to COPD, Sandy has high blood pressure, high cholesterol, and gastroesophageal reflux disease
Medications	<ul style="list-style-type: none"> • Branded products for COPD and shortness of breath • Generic products for high blood pressure, high cholesterol, and gastroesophageal reflux disease

Estimated Total Patient Out-of-Pocket Costs for 2022

Baseline 2022	H.R. 3	H.R. 19
\$2,170	\$2,000	\$1,495
<i>Cost Savings Compared to Baseline</i>		
<i>Baseline</i>	-\$170	-\$675

Sandy's Month-to-Month OOP Costs (COPD)



Green indicates OOP cap hit

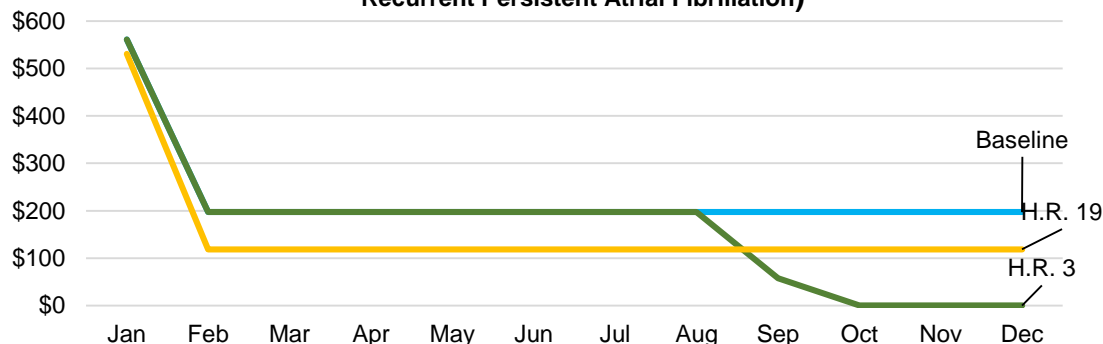
History of Hypertension and Recurrent Persistent Atrial Fibrillation

Patient	Ellen, age 68 from Charleston, SC
Disease Profile	Ellen has a history of hypertension and recurrent persistent atrial fibrillation
Medications	<ul style="list-style-type: none"> • Branded product for recurrent persistent atrial fibrillation • Generic products for blood pressure and to prevent blood clots

Estimated Total Patient Out-of-Pocket Costs for 2022

Baseline 2022	H.R. 3	H.R. 19
\$2,730	\$2,000	\$1,835
<i>Cost Savings Compared to Baseline</i>		
Baseline	-\$730	-\$895

Ellen's Month-to-Month OOP Costs (History of Hypertension/ Recurrent Persistent Atrial Fibrillation)



Green indicates OOP cap hit

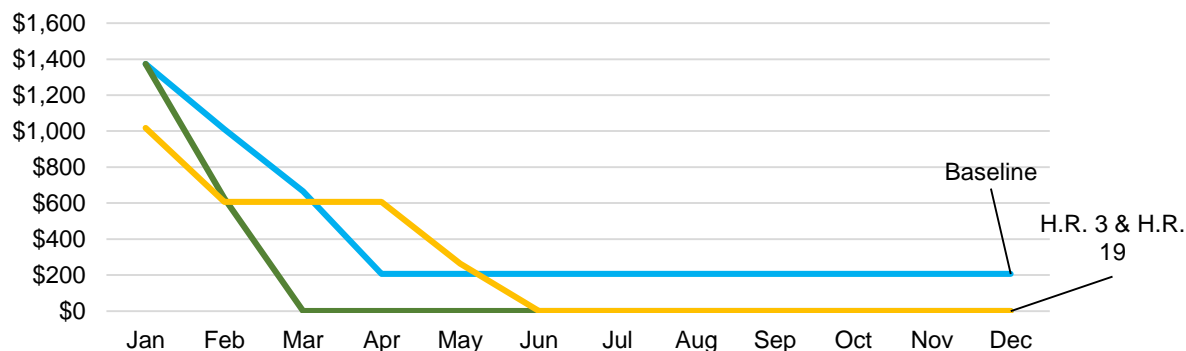
Human Immunodeficiency Virus (HIV)

Patient	Larry, age 67 from Louisville, Kentucky
Disease Profile	Larry is largely adherent to medications for his HIV, which he acquired during his 50s
Medications	<ul style="list-style-type: none"> • Branded products for HIV infection • Generic product for HIV treatment-related dyslipidemia from prior protease inhibitor regimen

Estimated Total Patient Out-of-Pocket Costs for 2022

Baseline 2022	H.R. 3	H.R. 19
\$4,905	\$2,000	\$3,100
<i>Cost Savings Compared to Baseline</i>		
<i>Baseline</i>	<i>-\$2,905</i>	<i>-\$1,805</i>

Larry's Month-to-Month OOP Costs (HIV)



Note: Month-to-Month does not reflect potential of beneficiary choice to “smooth” (spread out payments over remainder of year)

Green indicates OOP cap hit

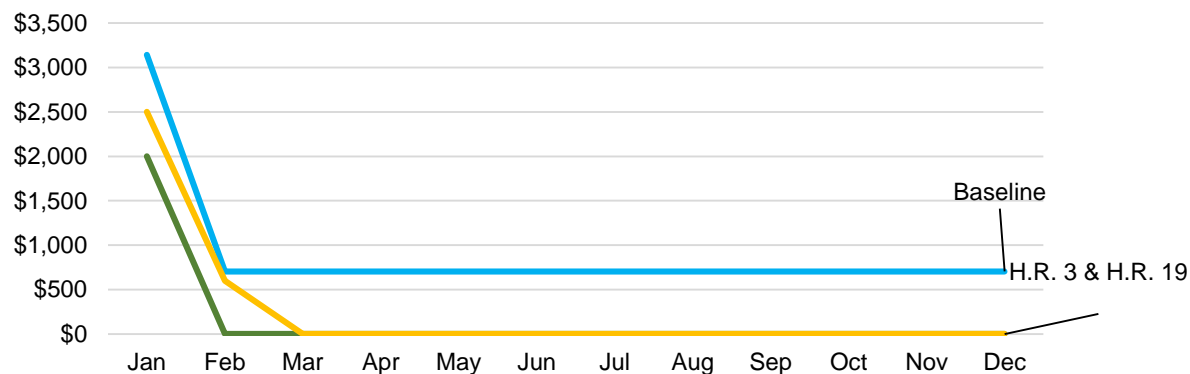
Metastatic Breast Cancer

Patient	Denise, age 66 from Basking Ridge, New Jersey
Disease Profile	Denise has hormone receptor-positive metastatic breast cancer (MBC), which progressed after she initially received treatment at age 62 for stage 3 disease. In addition to MBC, Denise has osteopenia and high blood pressure but is otherwise healthy
Medications	<ul style="list-style-type: none"> • Branded product for MBC • Generic products MBC and high blood pressure

Estimated Total Patient Out-of-Pocket Costs for 2022

Baseline 2022	H.R. 3	H.R. 19
\$10,890	\$2,000	\$3,100
<i>Cost Savings Compared to Baseline</i>		
<i>Baseline</i>	-\$8,890	-\$7,790

Denise's Month-to-Month OOP Costs (Metastatic Breast Cancer)



Note: Month-to-Month does not reflect potential of beneficiary choice to "smooth" (spread out payments over remainder of year)

Green indicates OOP cap hit

Thank you

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HEALTH COVERAGE